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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,942	12/10/2003	Edward C. Benzel	AXM-6666	6468

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EXAMINER	
HARVEY, JULIANNA NANCY	

ART UNIT	PAPER NUMBER
3733	

MAIL DATE	DELIVERY MODE
08/06/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/731,942	BENZEL ET AL.	
	Examiner	Art Unit	
	Julianna N. Harvey	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-16,19-23 and 25-34* is/are rejected.

7)☐ Claim(s) *3,4,17,18 and 24* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Inventorship

The examiner acknowledges that the correct spelling of the inventor is "Kari Zimmers" as indicated in the Declaration and confirmed by Applicant.

Specification

Title

In light of Applicant's amendment to the title, the objection to the title as stated in the 7 January 2008 Action has been withdrawn.

Abstract

The objection to the abstract as stated in the 7 January 2008 Action has been withdrawn.

Claim Objections

In light of Applicant's amendment to claims 31 and 33, the objection to these claims as stated in the 7 January 2008 Action has been withdrawn.

Claim 34 is objected to because of the following informalities: the word "retain" should be "retaining" (line 2). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 34 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The method, as indicated in claim 1, is directed toward a method for replacing a damaged spinal disc. Based on Applicant's specification, fixedly connecting the first and second retaining members to the core seems to occur during the method of manufacturing the artificial disc (page 12, lines 3-12). Further based on the specification, it seems that the surgeon receives the disc already assembled, meaning with the core already fixedly connected to the retaining members. As such, it seems that Applicant is combining claims directed toward a method of implanting an artificial disc with claims directed toward a method of manufacturing an artificial disc.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 5-12, 15, 16, 19-22, and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bryan et al. (US 6,156,067 A).

Regarding **claim 1**, Bryan et al. disclose an apparatus for replacing a damaged spinal disc in a spinal column wherein the apparatus comprises: an artificial disc including a resilient core having a first surface and a second surface, a first retaining member connected (defined by Merriam-Webster as "joined or linked together"; join is defined by Merriam-Webster as "to put or bring together so as to form a unit") to the first surface of the resilient core, and a second retaining member connected to the second surface of the resilient core, the first retaining member having an outer surface engageable with a first vertebra of the spinal column and an inner surface facing the first surface of the resilient core, the second retaining member having an outer surface engageable with the second vertebra of the spinal column and an inner surface facing the second surface of the resilient core; and a first mounting member comprising an anchor portion and a screw portion (Fig. 3 inset). Bryan et al. disclose connecting the first mounting member (anchor portion) with the first vertebra of the spinal column and moving the artificial disc into position between the first and second vertebrae (col. 6, line 54 through col. 7, line 9). Bryan et al. do not explicitly disclose moving the artificial disc into engagement with the first mounting member to guide the artificial disc into position between the first and second vertebrae. However, it is obvious that Bryan et al. do that as the opening in the artificial disc must be lined up with the opening in the anchor portion for the entire device to be properly implanted. As such, the opening in the anchor portion, because this portion of the mounting member is implanted first, acts as

a guide, visual or otherwise, when the artificial disc is inserted and comes into contact with the anchor portion. This guide ensures that the artificial disc is in the proper position between the vertebrae. Regarding **claim 2**, it is obvious that Bryan et al. engage the first mounting member with a guide on the first retaining member, the guide on the first retaining member being the opening that receives the screw portion of the mounting member, to guide movement of the first retaining member into position between the first and second vertebrae (see claim 1 above for further explanation). Regarding **claim 5**, it is obvious from Fig. 3 that Bryan et al. engage the first mounting member (screw portion) with a stop (frustoconical surface at the opening) on the first retaining member to prevent relative movement between the first retaining member and the first mounting member in a first direction ("Y" in Fig. 3 inset). Regarding **claim 6**, it is obvious that Bryan et al. guide movement of the first retaining member relative to the first mounting member in a second direction ("X" in Fig. 3 inset) extending transverse to the first direction (col. 6, line 54 through col. 7, line 9). Regarding **claim 7**, it is obvious that Bryan et al. guide movement of the first mounting member (screw portion) into an opening in the first retaining member (Fig. 3 inset). Regarding **claim 8**, it is obvious that Bryan et al. would engage the first mounting member (screw portion) with a surgical tool for connecting the first mounting member to the first vertebra as the screw head has a recess, which is commonly used to receive a tool to drive the screw, and inserting such a small screw is easier to do using a tool than by hand (Fig. 3 inset). Regarding **claim 9**, as stated above with respect to claim 8, it is obvious that a portion of the surgical tool would extend into a recess in the first mounting member (screw portion), which recess

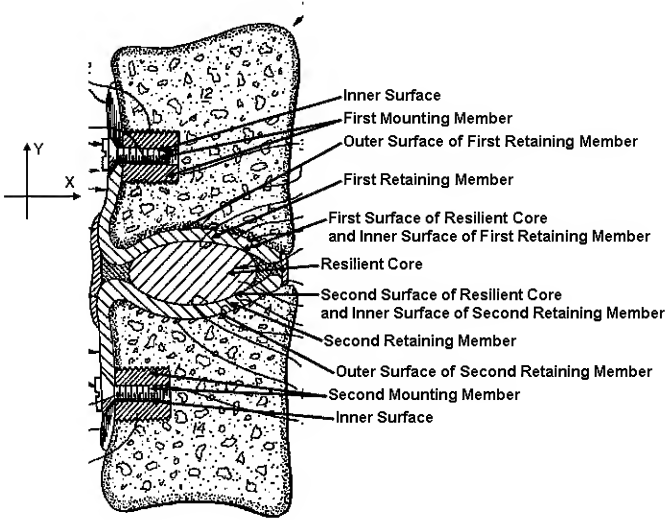
appears to be designed to receive a screwdriver (Fig. 3 inset and Fig. 1). Regarding **claim 10**, it is obvious that an inner surface of the first mounting member (anchor portion) that faces the core is spaced from the core (Fig. 3 inset). Regarding **claim 11**, Bryan et al. disclose connecting the artificial disc to the first mounting member (col. 6, line 54 through col. 7, line 9). Regarding **claim 12**, it is obvious that connecting the artificial disc to the first mounting member includes preventing movement of the first mounting member relative to the artificial disc as the screw portion would be tightened as much as possible to reduce the likelihood of screw loosening and backout.

Regarding **claim 15**, Bryan et al. disclose connecting a second mounting member (anchor portion) to the second vertebra and moving the artificial disc between the first and second vertebrae (col. 6, line 54 through col. 7, line 9). It is obvious that moving the artificial disc between the first and second vertebrae includes engaging the second mounting member with the artificial disc to guide movement of the artificial disc into position between the first and second vertebrae (see claim 1 above for further explanation). Regarding **claim 16**, it is obvious that Bryan et al. engage the first mounting member with a guide on the first retaining member, the guide on the first retaining member being the opening that receives the screw portion of the mounting member, to guide movement of the first retaining member into position between the first and second vertebrae and engage the second mounting member with a guide on the second retaining member, the guide on the second retaining member being the opening that receives the screw portion of the mounting member, to guide movement of the second retaining member into position between the first and second vertebrae (see

claim 1 above for further explanation). Regarding **claim 19**, it is obvious from Fig. 3 that Bryan et al. engage the first mounting member (screw portion) with a stop (frustoconical surface at the opening) on the first retaining member to prevent relative movement between the first retaining member and the first mounting member in a first direction ("Y" in Fig. 3 inset) and engage the second mounting member (screw portion) with a stop (frustoconical surface at the opening) on the second retaining member to prevent relative movement between the second retaining member and the second mounting member in the first direction ("Y" in Fig. 3 inset). Regarding **claim 20**, it is obvious that Bryan et al. guide movement of the first retaining member relative to the first mounting member in a direction ("X" in Fig. 3 inset) extending transverse to the first direction and guide movement of the second retaining member relative to the second mounting member in a direction ("X" in Fig. 3 inset) extending transverse to the first direction (col. 6, line 54 through col. 7, line 9). Regarding **claim 21**, it is obvious that Bryan et al. guide movement of the first mounting member (screw portion) into an opening in the first retaining member and guide movement of the second mounting member (screw portion) into an opening in the second retaining member (Fig. 3 inset). Regarding **claim 22**, it is obvious that Bryan et al. would connect the first mounting member (screw portion) with a surgical tool for connecting the first mounting member to the first vertebra and the second mounting member (screw portion) with the surgical tool for connecting the second mounting member to the second vertebra as the screw heads each have a recess, which is commonly used to receive a tool to drive the screw, and inserting such small screws is easier to do using a tool than by hand (Fig. 3 inset). Regarding **claim**

25, it is obvious that an inner surface of the first mounting member (anchor portion) that faces the core is spaced from the core and an inner surface of the second mounting member (anchor portion) that faces the core is spaced from the core (Fig. 3 inset). Regarding **claim 26**, Bryan et al. disclose connecting the artificial disc to the first and second mounting members (col. 6, line 54 through col. 7, line 9). Regarding **claim 27**, it is obvious that connecting the artificial disc to the first and second mounting members includes preventing movement of the first and second mounting members relative to the artificial disc as the screw portions would be tightened as much as possible to reduce the likelihood of screw loosening and backout.

FIG.3 **Bryan et al. (US 6,156,067 A)**



Claims 13, 14, and 28-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bryan et al. (US 6,156,067 A) as applied to claims 12 and 27 above, and further in view of Michelson (US 2002/0183757 A1). Regarding **claims 14** and **29**, Bryan et al. disclose engaging a frustoconical surface on the artificial disc with a frustoconical surface on the screw portions of the first and second mounting members

(col. 6, line 54 through col. 7, line 9; Fig. 3 inset above). Regarding **claims 13** and **28**, Bryan et al. teach the claimed invention except for connecting the artificial disc to the first and second mounting members with an interference fit. Michelson teaches a method of spinal stabilization wherein the resilient stabilization device (a plating system with movable plate segments) is connected to at least a first mounting member (a bone screw) with an interference fit (paragraphs 0078 and 0091). Regarding **claims 30-33**, Bryan et al. teach the claimed invention except for connecting a surgical tool to a first portion of the first retaining member and a first portion of the second retaining member by extending a first portion of the surgical tool into a first opening in the first portion of the first retaining member and a second portion of the surgical tool into a first opening in the first portion of the second retaining member. Michelson teaches a method of spinal stabilization wherein the resilient stabilization device (a plating system) is positioned by a surgical tool connected to the device by a first portion of the surgical tool extending into a first opening in the first portion of the first retaining member (plate) and a second portion of the surgical tool extending into a first opening in the first portion of the second retaining member (plate) (paragraphs 0079, 0082, and 0091; Fig. 13 inset). It would have been obvious to one of ordinary skill in the art at the time the invention was made to connect the Bryan et al. artificial disc to the Bryan et al. first and second mounting members (screw portions) with an interference fit (**claims 13** and **28**), as suggested by Michelson, as doing so would reduce the likelihood of screw backout. It would have been obvious to one of ordinary skill in the art at the time the invention was made to connect a surgical tool to a first portion of the Bryan et al. first retaining member and a

first portion of the Bryan et al. second retaining member by extending a first portion of the surgical tool into a first opening in the first portion of the Bryan et al. first retaining member and a second portion of the surgical tool into a first opening in the first portion of the Bryan et al. second retaining member (**claims 30-33**), as suggested by Michelson, as doing so would facilitate insertion of the retaining members.

Michelson (US 2002/0183757 A1)

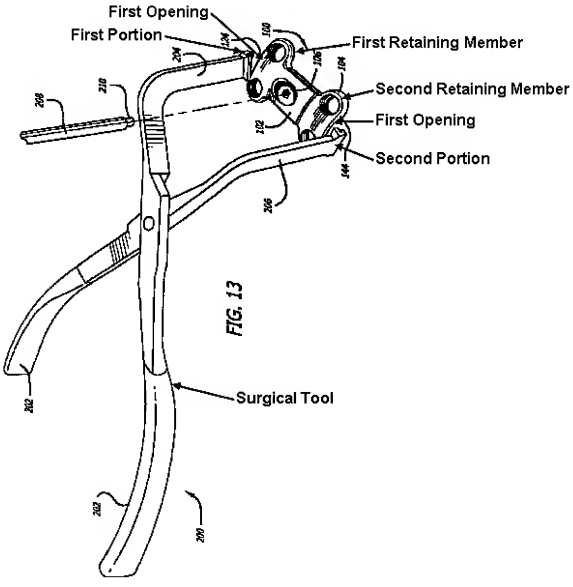


FIG. 13

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bryan et al. (US 6,156,067 A) as applied to claim 22 above, and further in view of Kambin (US 5,584,887 A). Bryan et al. teach the claimed invention except moving the first and second mounting members away from each other to connect the first and second mounting members to the first and second vertebrae. However, it is obvious that this occurs as manufacturers, when packaging products, group like pieces together. Kambin illustrates this showing a surgical kit containing an implant comprising numerous mounting members (1 in Fig. 9) which are grouped together in the kit. Kambin also shows that the mounting members are connected to first and second vertebrae (1 and 60 in Figs. 16 and 17). As such, some time during insertion, it is obvious that a first and second mounting member are moved away from each other to connect to the first and second vertebrae. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the Bryan et al. artificial disc, including mounting members, in a kit with like pieces grouped together such that the surgeon would move the first and second mounting members away from each other to connect the first and second mounting members to the first and second vertebrae, as suggested by Kambin, as such a kit enhances efficiency during the surgical procedure.

Allowable Subject Matter

Claims 3, 4, 17, 18, and 24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: no references, or reasonable combination thereof, could be found which disclose, or suggest, (a) engaging the first (claim 3) or first and second (claim 17) mounting members with a guide extending from the outer surface of the first (claim 3) or first and second (claim 17) retaining members and engaging the first (claim 3) or first and second (claim 17) vertebrae with the guide; (b) engaging the first (claim 4) or first and second (claim 18) mounting members with first and second guides extending generally parallel to each other on the first (claim 4) or first and second (claim 18) retaining members to guide movement of the first (claim 4) or first and second (claim 18) retaining members into position between the first and second vertebrae; and (c) extending a first portion of the surgical tool into a recess in the first mounting member and extending a second portion of the surgical tool into a recess in the second mounting member (claim 24).

Response to Arguments

Applicant's arguments, filed on 11 April 2008, with respect to the 35 USC § 112, second paragraph rejection of claim 23 have been fully considered and are persuasive. The rejection of claim 23 has been withdrawn.

Applicant's arguments filed 11 April 2008 with respect to the 35 USC § 102(b) rejection of claim 1 over Bryan et al. (US 6,156,067 A) have been fully considered but they are not persuasive.

Applicant first argues that the retaining members of Bryan et al. are not connected to the adjacent surfaces of the resilient core and states that this lack of connection is pointed out at col. 8, lines 3-5 and col. 7, lines 10-15 of Bryan et al. Applicant further states that the retaining members merely contact the adjacent surfaces of the resilient core so that relative sliding motion between the members and the core is possible. The examiner respectfully disagrees. The retaining members of Bryan et al. are connected to the core in that "connected", as defined by Merriam-Webster, means "joined or linked together", and "join", as defined by Merriam-Webster, means "to put or bring together so as to form a unit". The retaining members and core of Bryan et al. are clearly put together so as to form a unit, that unit being the artificial disc endoprosthesis. Furthermore, Applicant's addition of claim 34, which includes "fixedly connecting" the retaining members to the core, supports the examiner's interpretation of "connected" as defined by Merriam-Webster.

Applicant then argues that the Bryan et al. endoprosthesis is fully inserted between the two vertebrae before the retaining member contacts the mounting member, and as such, the endoprosthesis is not moved into engagement with the mounting member to guide the endoprosthesis into position between the first and second vertebrae. The examiner respectfully disagrees. As Bryan et al. indicate at col. 6, line 54 through col. 7, line 9, a portion (anchor 102) of the mounting member is first

implanted, then the opposing vertebral surfaces are milled and the endoprosthesis inserted, and finally the endoprosthesis is attached by the mounting member to the bone. This attachment is accomplished by a screw inserted through an opening in the endoprosthesis and secured within an opening of the anchor portion of the mounting member. Because of this, the opening in the endoprosthesis must be lined up with the opening in the anchor portion for the entire device to be properly implanted. As such, the opening in the anchor portion, because this portion of the mounting member is implanted first, acts as a guide when the endoprosthesis is inserted and comes into contact with the anchor portion. This guide ensures that the endoprosthesis is in the proper position between the vertebrae.

Applicant's arguments, filed 11 April 2008, with respect to the 35 USC § 103(a) rejection of claim 1 over Harrington (US 5,893,889 A) in view of Bryan et al. (US 6,156,067 A) have been fully considered and are persuasive. The rejection of claims 1-2, 4, 10, 15-16, 18, and 25 has been withdrawn.

Applicant's arguments, filed 11 April 2008, with respect to the 35 USC § 103(a) rejection of claims 3 and 17 over Harrington and Bryan et al. in view of Lego blocks and von Hoffmann et al. (US 2002/0143333 A1) have been fully considered and are persuasive. The rejection of claims 3 and 17 has been withdrawn.

Applicant's arguments with respect to the 35 USC § 103(a) rejection of claims 1 and 30-33 over Buttner-Janz et al. (US 5,401,269 A) in view of Bryan et al. (US 6,156,067 A) and Marnay (US 5,314,477 A) have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julianna N. Harvey whose telephone number is 571-270-3815. The examiner can normally be reached on Mon. - Fri., 8:00 a.m. - 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. N. H./
Examiner, Art Unit 3733
/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733